



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/700,507	11/05/2003	Ali Amara	03495.0301	6288

22852 7590 02/08/2008
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER
LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER

CHEN, STACY BROWN

ART UNIT	PAPER NUMBER
----------	--------------

1648

MAIL DATE	DELIVERY MODE
-----------	---------------

02/08/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

10/700,507

Applicant(s)

AMARA ET AL.

Examiner

Stacy B. Chen

Art Unit

1648

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 03 January 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
- a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on 31 January 2008. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
- (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ They raise the issue of new matter (see NOTE below);
- (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
- The status of the claim(s) is (or will be) as follows:
- Claim(s) allowed: 24,27-29,31-34,36,81,82,91,94-96,98-102,104,105,110 and 111.
- Claim(s) objected to: _____.
- Claim(s) rejected: 40.
- Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

Continuation of item 7: Applicant's after-final amendment filed January 3, 2008 is acknowledged and entered. The claims were not amended in the after-final amendment, however Applicant presents arguments rebutting the rejection of claim 40 under 35 U.S.C. 103(a) as obvious over Pass et al. (J. Infect. Dis., 1999, "Pass") in view of Cunningham et al. (NEJM, 1998, "Cunningham"). Applicant's arguments have been carefully considered, but fail to persuade.

Applicant argues that the Office has not properly set forth an inherency argument. Applicant points to *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1378 (Fed. Cir. 2005), "*Perricone*") as a basis for proving that the inherency argument is not proper in this case. Specifically, Applicant argues that the issue is not whether Pass' CMV vaccine comprising gB, if administered to a human would inherently treat an HIV infection, but whether Pass discloses the application of its gB composition to treat HIV infection. Applicant also argues that Cunningham's disclosure regarding CMV retinitis affecting 30-40% of HIV-positive patients, does not compensate for the inadequacy of Pass' disclosure because not every HIV-infected individual has CMV.

In response to these arguments, the Office recognizes that new uses of old products may be patentable. The Office has determined that given Cunningham's disclosure regarding the 30-40% rate of CMV retinitis in HIV-infected individuals, it would have been obvious to administer Pass' vaccine to HIV-infected individuals. One must consider the patient population involved in this case. The simple facts are as follows: Pass' vaccine is for the prevention of CMV infection. Cunningham teaches that 30-40% of HIV-infected individuals (whose CD4+ T cells have fallen below a certain level) are affected by CMV retinitis. It would have been obvious to prevent CMV infection in HIV-infected individuals by administering Pass' vaccine, since 3 to 4 people out of 10 will develop CMV retinitis. Although not every HIV-infected individual will become infected with CMV, note that 3 or 4 people out of 10 are not an insignificant number. By administering Pass' vaccine to HIV-infected individuals, one would inherently treat HIV in HIV-infected individuals. Therefore, the rejection is maintained for reasons of record.

Applicant remarks that the final action by the Office presented a new argument as to the application of the art against Applicant's invention. In response, it is the Office's position that no new argument was presented in the final rejection because the rejection/reasoning set forth in the non-final action of 12/20/06 is identical to the rejection in the final action of 8/3/07. As for the Office's reply in the final action to Applicant's arguments, the reasoning behind those remarks is merely a further reiteration of the points that were made in the non-final and final rejections, not considered to be new arguments.

/Stacy B. Chen/ 2-4-2008
Primary Examiner, TC1600